
OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

Q SUBMISSIONS: AGENCY-INITIATED ACTIONS

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I. PURPOSE

This document describes how to add documents or other information to the administrative record of (abbreviated) new animal drug applications ((A)NADAs), (generic) investigational new animal drug ((J)INAD) files, and veterinary master files (VMF) when the documents are not associated with an open or pending submission from the sponsor.

II. BACKGROUND

Before August 1994, Submission Tracking and Reporting System-tracked (STARS) submissions were restricted to submissions from the sponsor (or outside agencies) to a file or application. If the Center for Veterinary Medicine (CVM) or the agency initiated work that was not associated with a sponsor's submission, there was no readily available and searchable record of that work. The records resulting from that work (e.g., letters, memoranda) were filed in the administrative record of the associated application or file and could only be found by a manual search or direct knowledge of the record in an administrative file. We established the Q submission type in STARS to enable us to track and search for CVM-initiated actions in STARS.

III. TYPES OF Q SUBMISSIONS

Q submissions are most commonly created to:

- prepare a Freedom of Information (FOI) Summary when a (J)INAD project is nearing completion (see Policies and Procedures (P&P) 1243.5761);
- document internal meetings to discuss the status of each technical section for a (J)INAD project at end (endgame) of the project (see P&P 1243.3051);
- document telephone or email correspondence with a sponsor regarding an application or file but unrelated to an open or pending submission;
- capture any other record CVM initiates and creates that is not directly related to the review of an open or pending submission and is relevant to one or more applications or files. For example, reviews of veterinary master file (VMF) submissions that were closed out with final action codes such as FNR/MEMO or ACK and not previously reviewed; and

- outline file naming conventions when combining or transferring files (per SOP 1243.182.002).

IV. CREATING THE Q SUBMISSION

A. When Do We Create a Q Submission

Create a Q submission when the need is first identified. Set a reasonable CVM due date for completion of review and preparation of review documentation, taking into consideration any consulting review due dates (75% of the STARS due date) or the due date for any related submissions.

B. How Do We Create a Q Submission

Use the ONADE Create Q Submission workflow in Appian. Access this workflow from the Actions tab. Enter the required information into the fields and select an appropriate due date. In the Purpose of Submission field on the Entry Form, select an option from the drop-down list. If none of the items in the list are applicable, select Other and enter a short descriptive phrase (e.g., “document stats analysis discussion for Study 1234” rather than just “memo to file”) into the text field provided. Adding an accurate description will help identify the purpose of submission in STARS. There is a limit of 73 characters when creating a custom purpose of submission. You may assign the submission to yourself or request that it be assigned to someone else. You may also choose to send a notification to others that the submission has been created. As the workflow initiator, you automatically receive an email confirmation. If you assign the submission to yourself, STARS automatically adds it to your queue. If you request to assign the submission to someone else, the submission appears as unassigned in the STARS Primary Reviewer Assignments screen of the division selected during the workflow.

C. Preparing Review Documentation and Final Action Processing for the New Q Submission

Proceed with the review and processing of the Q submission in a manner similar to other submissions, recognizing its due date and potential priority within CVM. Q submission due dates can be updated at any time during the review cycle. Final out the submission as consistent with current policy (see P&P 1243.3030). Q submissions are most commonly finalized out with FNR/MEMO or ACK.

V. REFERENCES

CVM Program Policy and Procedures Manual:

1243.3030 – Completing Final Action Packages for STARS Submissions

1243.5761 – FOI Summary for Original and Supplemental NADAs

1243.5762 – Freedom of Information (FOI) Summary for an Animal Drug Availability Act (ADAA) Medicated Feed Combination New Animal Drug Application

1243.3051 – Verifying Scope and Technical Section Status for Phased Review ((J)INAD) Projects in the End Game

ONADE Standard Operating Procedure

1243.182.002 – Combining and Transferring Files

VI. VERSION HISTORY

March 29, 2011 – original version

July 25, 2011 – Updated to Verdana font, clarified location of the Agency-Initiated Action Submission Form, updated the types of Q submissions

August 26, 2014 - Updated to reflect the addition of an Appian workflow for the creation of Q submissions.

June 15, 2016 – Updated format

August 6, 2018 - Revised to remove reference to a P&P that was retired. Updated to current P&P format and update section IV. B. to reflect current Appian information.

November 24, 2021 – Add reference to new SOP 1243.182.002 Combining and Transferring Files.

July 15, 2022 – Quality system review for minor formatting updates.

August 10, 2023 - Quality system review conducted of the document and no updates or revisions were necessary at this time. To bring all office quality system documentation into compliance with the FDA Visual Identity Program approved fonts, ONADE has adopted Arial 11-point font. The font of this document was changed from Verdana 10-point font to Arial 11-point font.

October 18, 2023 – Updating section III to correct a typographical error in the number given for the P&P on FOI Summaries. Changed it from to 1243.5731 to the correct number 1243.5761.